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UNITED STATES DISTRICT COURT

NORTHERN DISTRICT OF CALIFORNIA

SAN FRANCISCO DIVISION

UNITED STATES OF AMERICA, Plaintiff, v. SCANDINAVIAN SMOKE HOUSE, INC., a corporation, and ODD ANDERS HOLM, an individual, Defendants.	Case No. 3:06-cv-6610-EMC

CONSENT DECREE OF PERMANENT INJUNCTION

Plaintiff, the United States of America, by its undersigned counsel, having filed a complaint for injunctive relief against Scandinavian Smoke House, Inc. ("Scandinavian Smoke House") and Odd Anders Holm (collectively, "defendants"), and defendants having appeared and having consented to entry of this Decree without contest and before any testimony has been taken, and the United States of America having consented to this Decree:

IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that:

1. This Court has jurisdiction over the subject matter and over all parties to this action.

2. The complaint for injunction states a claim for relief against defendants under the Federal Food, Drug, and Cosmetic Act (the "Act"), 21 U.S.C. § 301 (2000) et seq.

3. Defendants violate the Act, 21 U.S.C. § 331(a), by causing to be introduced into interstate commerce articles of food, as defined by 21 U.S.C. § 321(f), namely cold-smoked fishery products, that are adulterated within the meaning of 21 U.S.C. § 342(a)(1) and 21 U.S.C. § 342(a)(4); and 21 U.S.C. § 331(k), by causing articles of food, cold-smoked fishery products, to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) and 21 U.S.C. § 342(a)(4) after shipment in interstate commerce.

4. Defendants represent to the Court that, at the time of entry of this Decree, they are not engaged in processing, preparing, packing, holding, or distributing any type of food. If defendants later intend to resume processing, preparing, packing, holding, or distributing food, they must first notify the United States Food and Drug Administration ("FDA") in writing at least ninety (90) calendar days in advance of resuming operations what type(s) of food defendants intend to process and distribute and whether they intend to proceed under paragraph 5 herein. Defendants shall not resume operations until receiving written notice from FDA, as required by paragraph 5(H) of this Decree, and then shall resume operations only to the extent authorized in the written notice from FDA.

5. Defendants and each and all of their officers, agents, employees, successors, assigns, attorneys, and those persons in active concert or participation with any of them, are perpetually restrained and enjoined under the provisions of 21 U.S.C. § 332(a) from processing, preparing, packing, holding, or distributing, at or from their facility located at 250 Napoleon Street, Unit M, San Francisco, California, and any new locations at or from which defendants process, prepare, pack, hold, or distribute food, including any cold-smoked fishery products. This perpetual restraint and injunction shall continue until:

(A) Defendants thoroughly clean and sanitize the facility and equipment therein, and made improvements, thereby rendering the facility and equipment suitable for processing, preparing, packing, holding, and distributing articles of food;

(B) Defendants select a person ("*Listeria* expert"), who is without any personal or financial ties (other than a consulting agreement) to the defendants or their families, and who, by reason of background, experience and education, is qualified to develop a raw ingredient testing program, a Sanitation Standard Operation Procedure ("SSOP"), an employee training program on sanitary food handling techniques and personal hygiene practices, and an environmental microbial monitoring program for the *Listeria* genus ("*L. spp.*") for the processing of cold-smoked fishery products;

(C) The *Listeria* expert develops a written raw ingredient testing and treatment program for *Listeria monocytogenes* ("*L. monocytogenes*"), an SSOP, an employee training program, and an environmental microbial monitoring program for *L. spp.* for the processing of cold-smoked fishery products;

(D) FDA approves in writing the raw ingredient testing and treatment program, SSOP, training program, and environmental microbial monitoring program developed by the *Listeria* expert;

(E) Defendants conduct appropriate hazard analyses and prepare Hazard Analysis Critical Control Point ("HACCP") plans as required by 21 C.F.R. § 123.6(b) for all foods processed at the facility, including all cold-smoked fishery products; said analyses and plans must be performed and designed to the satisfaction of FDA;

(F) FDA, as it deems necessary to evaluate defendants' compliance with the terms of this paragraph 5, conducts inspections of the facility;

(G) Defendants pay the costs of inspections, supervision, analyses, and examination by FDA at the rates specified in paragraph 8; and

(H) FDA notifies defendants in writing that defendants appear to be in compliance with the requirements set forth in paragraphs 5(A)-(G) and with all requirements of 21 C.F.R. Parts 110 and 123.

6. After completing the requirements of paragraph 5, and upon resuming operations, defendants shall implement an ongoing program of adequate measures to control *L. monocytogenes* ("*Listeria* program"). The *Listeria* program shall include the following procedures, unless defendants submit for and receive FDA's written approval an alternative *L. monocytogenes* control program, consisting of validated methods and controls, that is shown to FDA's satisfaction to eliminate *L. monocytogenes* in the finished product:

(A) Treatment or testing of susceptible raw ingredients for cold-smoked fish products. Raw material testing for *L. monocytogenes* shall be performed in accordance with timetables and methods submitted to and approved in writing by FDA before testing begins. Defendants shall select a competent, independent laboratory to perform the testing. The name of the laboratory shall be submitted to FDA before testing begins. The results of all testing conducted pursuant to this paragraph shall be submitted to FDA within two (2) calendar days after receipt by defendants. Where a sample analysis shows the presence of *L. monocytogenes* in any raw ingredient, the finished product lot made in whole or in part from that raw ingredient shall be placed on hold or recalled, as FDA deems appropriate, and shall, as FDA deems appropriate, be destroyed by defendants under FDA's supervision, or reconditioned under FDA's supervision pursuant to a reconditioning plan approved by FDA. All expenses of such supervision, analyses, and examination by FDA shall be paid by defendants at the rates specified in paragraph 8;

(B) Effective and diligent sanitation procedures for cleaning and sanitizing manufacturing equipment and environment to minimize the risk of reintroducing *L. monocytogenes*. These procedures shall consist of the SSOP and the training program developed

by the *Listeria* expert pursuant to the provisions of paragraph 5 and shall be implemented on a continuous basis;

(C) An effective program for environmental monitoring and testing of manufacturing and storage environment to ensure that *L. spp*. are controlled within the facility and *L. monocytogenes* does not occur in the finished product. The ongoing environmental microbial monitoring program shall ensure that the SSOP continues to eliminate the *L. monocytogenes* hazard and that the SSOP is consistently being followed. Environmental monitoring shall include collecting swab samples from food contact surfaces, equipment, and other environmental sites throughout the facility (where the fish is received, prepared, packed, and held, up to and including final packaging, and common areas that could be reservoirs for cross-contamination), and analyzing such samples for the presence of *L. spp*. Environmental testing for *L. spp.* shall be performed in accordance with timetables and methods submitted to and approved in writing by FDA before testing begins. Defendants shall select a competent, independent laboratory to perform the testing and submit the name of the laboratory to FDA before testing begins. The results of all testing conducted pursuant to this paragraph shall be submitted to FDA within two (2) calendar days after receipt by defendants;

(D) Additional finished product control measures. Defendants shall implement additional control measures to prevent growth of *L. monocytogenes* in finished products. Defendants shall notify FDA regarding the control method they select. These control measures shall continue until, in the finished product testing described in paragraph 6(E), the laboratory test results continuously do not show the presence of *L. monocytogenes* for six consecutive months. If, after such six-month period, a laboratory test result shows the presence of *L. monocytogenes*, defendants shall resume the additional finished product control measures under this paragraph and continue them until the laboratory test results continuously do not show the presence of *L. monocytogenes* for six consecutive months; and

(E) Finished product testing. Defendants shall test finished products as follows:

(i) immediately upon resuming operations and after completing the requirements in paragraph 5, defendants shall test for *L. monocytogenes* in each lot of finished product for at least five consecutive production days;

(ii) immediately after the completion of testing under paragraph 6(E)(i), defendants shall test at least one lot per day for at least the next 20 production days;

(iii). immediately after the completion of testing under paragraph 6(E)(ii), defendants shall test at least one lot per every five production days for the next three months; and

(iv) immediately after the completion of testing under paragraph 6(E)(iii), defendants shall test at least one lot during each three month period thereafter.

If any laboratory test listed in subparagraphs 6(E)(i)-(iv) shows the presence of *L. monocytogenes* in any product, defendants must, before resuming any production, determine and correct the cause of the microbial contamination and start the complete sequence of testing again.

7. Within thirty (30) days of the entry of this Decree, all food that is in the defendants' possession at the time this Decree is signed by the parties shall be destroyed by the defendants, at their own cost and under FDA's supervision, or reconditioned under FDA's supervision pursuant to a reconditioning plan approved in writing and in advance by FDA.

8. Defendants shall pay the costs of FDA's supervision, inspection, review, examination, and analyses conducted pursuant to this Decree at the standard rates prevailing at the time the activities are accomplished. As of the date this Decree is signed by the parties, these rates are: $76.10 per hour and fraction thereof per representative for inspection and supervision work other than laboratory and analytical work; $91.18 per hour and fraction thereof per representative for laboratory and analytical work; $0.445 per mile for travel by automobile; the government rate or equivalent for travel by air; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day per representative for subsistence expenses, where necessary. In the event that the standard rates generally applicable to FDA supervision,

inspection, review, examination, or analysis are modified, these rates shall be increased or decreased without further order of the Court.

9. Duly authorized representatives of FDA shall be permitted, as FDA deems necessary and without prior notice, to make inspections of the defendants' facilities, including any new locations, and all equipment, finished and unfinished materials and products, containers, labeling and other promotional material; to take photographs and make videotape recordings; to collect samples of any finished and unfinished materials and products, containers, and labeling; and to examine and copy all records relating to the receipt, processing, packing, labeling, promotion, holding and distribution of any and all of the defendants' products to ensure continuing compliance with the terms of this Decree. During inspections, defendants shall cooperate fully with the FDA, by, among other things, promptly providing FDA investigators with requested documents and materials. The costs of all such inspections, supervision, review, examination, and analyses are to be borne by defendants at the rates specified in paragraph 8. The inspections shall be permitted upon presentation of a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is apart from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

10. After the requirements of paragraph 5(A)-(G) are met, defendants and each and all of their officers, agents, employees, successors, assigns, attorneys, and those persons in active concert or participation with any of them, are permanently restrained and enjoined from doing or causing to be done, directly or indirectly, any act that violates 21 U.S.C. § 331(a), by causing the introduction into interstate commerce articles of food that are adulterated within the meaning of 21 U.S.C. § 342(a)(1) or 21 U.S.C. § 342(a)(4); and 21 U.S.C. § 331(k), by causing articles of food to become adulterated within the meaning of 21 U.S.C. § 342(a)(1) or 21 U.S.C. § 342(a)(4) after shipment in interstate commerce.

11. If, at any time after entry of this Decree, FDA determines, based on the results of an inspection, analysis of a sample or samples, or other information, that the defendants have failed

to comply with any provision of this Decree, have violated FDA regulations or the Act, or that additional corrective actions are necessary to achieve compliance with this Decree, FDA regulations, or the Act, FDA may, as and when it deems necessary, notify the defendants in writing of the noncompliance and order the defendants to take appropriate action, including, but not limited to, ordering the defendants to immediately take one or more of the following actions:

(A) Cease receiving, processing, preparing, packing, holding, and distributing any article of food;

(B) Recall all articles of food that have been distributed or are under the custody and control of defendants' agents, distributors, customers, or consumers; or

(C) Take any other corrective actions as FDA deems necessary to bring the defendants into compliance with this Decree, FDA regulations, and the Act.

Defendants shall pay all costs of such recalls and corrective actions, including the costs of FDA supervision, inspections, analyses, examinations, review, travel, and subsistence expenses to implement recalls and other corrective actions, at the rates specified in paragraph 8. This provision shall be separate and apart from, and in addition to, all other remedies available to FDA.

12. Any cessation of operations as described in paragraph 11 shall continue until defendants receive written notification from FDA that defendants appear to be in compliance with the Decree, FDA regulations, and the Act. After a cessation of operations, and while determining whether defendants are in compliance with the Decree and the Act, FDA may require that defendants re-institute or re-implement any of the requirements of this Decree.

13. Defendants shall maintain copies of their HACCP plans, along with copies of any HACCP records required by the plans and by 21 C.F.R. §§ 123.6(c)(7), 123.7(d) and 123.8(d), at their facility in a location where they are readily available for reference and inspection by FDA officials. All records required to be kept by the HACCP plans and by these sections of the Code

of Federal Regulations shall be retained for at least three (3) years after the date the records are prepared.

14. All decisions specified in this Decree shall be vested in the discretion of FDA. FDA's decisions shall be final and, to the extent that these decisions are subject to review, shall be reviewed by the Court under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based on the written record before FDA at the time the decision was made. No discovery shall be had by either party.

15. Defendants shall provide a copy of this Decree to each of defendants' directors, officers, and employees within ten (10) calendar days from the date of entry of this Decree by the Court, and shall provide to FDA within thirty (30) calendar days of the date of entry of this Decree, an affidavit of compliance with this paragraph stating the fact and manner of compliance and identifying the names and positions of all persons so notified.

16. Defendants shall, in writing, notify FDA at least thirty (30) calendar days before any change in ownership, character, or name of Scandinavian Smoke House, including reorganization, relocation, dissolution, assignment, or sale resulting in the emergence of a successor entity or corporation; the creation or dissolution of subsidiaries or any other change in athe corporate structure or identity of Scandinavian Smoke House; or the sale or assignment of any business assets, such as buildings, equipment, or inventory that may affect obligations arising out of this Decree. Defendants shall serve a copy of this Decree on any prospective successor or assign no later than thirty (30) calendar days prior to such sale or change in business and shall furnish FDA with an affidavit of compliance with this paragraph within fifteen (15) calendar days of such service on a prospective successor or assign.

17. Any notices, test results or other information this Decree requires defendants to give to FDA shall be given in writing to the District Director, FDA San Francisco District Office, 1431 Harbor Bay Parkway, Alameda, CA 94502-7070.

18. Plaintiff, the United States, shall have and recover from defendants the costs of this action as taxed by the Court.

19. Should the United States bring, and prevail in, a contempt action to enforce the terms of this Decree, defendants agree to pay attorneys' fees (including overhead), travel expenses incurred by attorneys and witnesses, court costs, expert witness fees and investigational and analytical expenses incurred in bringing such action.

20. This Court shall retain jurisdiction of this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

SO ORDERED:

Dated this ___lst___ day of _____December_____, 2006.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF CALIFORNIA
IT IS SO ORDERED
Judge Edward M. Chen

_____
UNITED STATES DISTRICT JUDGE
MAGISTRATE

We hereby consent to the entry of the foregoing Decree.

FOR DEFENDANTS:

Dated: October _____, 2006

_____
ODD ANDERS HOLM,
individually and on behalf of Scandinavian Smoke House, Inc.

Dated: October _____, 2006

_____
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Dated: October 24, 2006

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